

REMARKS

Reconsideration and withdrawal of the objections to and the rejections of this application in view of the amendments and remarks herewith, is respectfully requested, as the application is believed to be in condition for allowance.

I. Status of the Claims and Formal Matters

Claims 1, 5-26, 28-32 and 38-60 are under examination in this application upon entry of the amendments presented herein. Claims 1, 25, 28, 32, 38, 40, 45, 46, 50, 54, 55 and 58 are amended and new Claims 59 and 60 are added. It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112.

Support for the claim amendments herein can be found throughout the specification. For example: support for Claim 1 can be found in paragraphs 71-78 and in Figure 3; support for Claim 25 can be found in paragraphs 97 and 109; support for Claim 28 can be found in paragraphs 196-197; support for Claim 32 can be found in paragraphs 71-78 and 196-197 as well as in Figure 3; and support for Claim 58 can be found in paragraphs 97 and 109.

II. THE REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME

A. Rejection of Claims 1, 5-26, 28-32 and 38-58 under 35 U.S.C. § 112, First Paragraph.

Claims 1, 5-26, 28-32 and 38-58 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Amended Claim 1 now recites further details related to the photoresist processing technique in accordance with the teachings of paragraphs 75-78 and Figure 3. Claim 1 is now believed to be very commensurate in breadth and scope with the specification. Accordingly, the rejection under 35 U.S.C. § 112, first paragraph, with respect thereto has been obviated and withdrawal thereof is respectfully requested.

Amended Claim 40 recites the details of fabricating the second layer in a similar manner to that of fabricating the first layer. The suggestion for this is found in paragraph 75, first and last sentences as well as shown in the lowermost, right-hand side of Figure 3 in which the first and second layers are basically the same. Accordingly, the rejection under 35 U.S.C. § 112, first

paragraph, with respect to Claim 40 has been obviated and withdrawal thereof is respectfully requested.

Claim 28 was rejected under the proposition that the specification does not support simply reciting “a semiconductor manufacturing process”. The applicants’ representative respectfully disagrees. This term is very well understood by those of ordinary skill. For example, a simple google search of this term yields a very long list of uniform citations. Each refers to the process of making computer chips or integrated circuits. Many of the hits go into great detail, as does the subject application. For example, the subject application details how wafers are coated and patterned to form microstructures in paragraphs 153-163 among many other places. As such, there is no doubt as to the meaning of “a semiconductor manufacturing process”, namely, a process that supports fabrication of computer chips/integrated circuits. By having multiple such processes clearly described in the specification as noted, there is ample support for this claim limitation. Accordingly, the rejection under 35 U.S.C. § 112, first paragraph, with respect to Claim 28 is improper and withdrawal thereof is respectfully requested.

Amended Claim 32 now recites further detail in that the microfluidic pattern is optically created in a light sensitive material such as described, without limitation, at paragraphs 72 and shown in Figure 3 of the subject application. In view of this clear support, Claim 32 is believed to be very commensurate in breadth and scope with the specification. Accordingly, the rejection under 35 U.S.C. § 112, first paragraph, with respect to Claim 32 has been obviated and withdrawal thereof is respectfully requested.

Amended Claim 50 now recites further detail related to thick resist processing as described in paragraph 97. Accordingly, the rejection under 35 U.S.C. § 112, first paragraph, with respect thereto has been obviated and withdrawal thereof is respectfully requested.

Amended Claim 25 recites, *inter alia*, the polymer scaffold is approximately 10 to 500 microns thick. Support for this can be found at paragraph 97 among other places. Claim 25 also recites the channels are about 200 microns in width. Support for this can be found at paragraphs 78, 109, 154, 157-159, 183-185, 193 and 196. Claim 25 also recites the channels are about 10 to 50 microns in depth. Support for this can be found at paragraphs 78, 109, 159, 162, 183-185, 193 and 196. Claims 45 and 58 recites similar limitations. Accordingly, the rejection under 35

U.S.C. § 112, first paragraph, with respect to Claims 25, 45 and 58 is improper and withdrawal thereof is respectfully requested.

Claim 39 is supported by the first sentence of paragraph 75 and paragraph 10. Claims 40, 41, 46 and 49 are supported by Figure 3 and the associated description. Claim 43 is supported by paragraph 76. Claim 44 is supported by paragraph 10. Claims 47 and 48 are supported by paragraphs 157-160. Claim 50 is supported by the first sentence of paragraph 75, paragraph 10, Figure 3 and the associated description. Claim 51 is supported by paragraph 59. Claim 52 is supported by paragraph 97. Claim 53 is supported by paragraph 196. Claims 54, 56 and 57 are supported by originally filed Claim 32. Claim 55 is supported by paragraphs 63 and 64. Accordingly, the rejection under 35 U.S.C. § 112, first paragraph, with respect to these claims is improper and withdrawal thereof is respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. § 103 ARE OVERCOME

A. Rejection of Claims 1, 2, 5-26, 28-32 and 38.

Claims 25, 26, 49 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,143,293 to Weiss et al. in view of U.S. Patent No. 6,139,574 to Vacanti et al. and U.S. Patent No. 6,136,212 to Mastrangelo et al., and if necessary, U.S. Patent No. 5,518,680 to Cima et al. and U.S. Patent No. 6,165,486 to Marra et al. Applicants respectfully traverse the rejection.

Weiss et al. discloses low precision devices produced by standard polymer fabrication techniques, which are joined together by polymer attachment methods such as barbs. Microfabrication is only indirectly referred to as a method to produce "barbs" or interconnects which join layers. Weiss does not propose the use of microfabrication to form patterned microchannels. There is no teaching or suggestion in Weiss et al. to make a polymer scaffold in a mold as recited in the present claims.

Mastrangelo et al. merely provide polymer layers stacked on top of a rigid substrate to create microfluidic devices such as an inkjet printhead. The silicon wafer of Mastrangelo et al. forms part of the structure. There is no teaching or suggestion in Mastrangelo et al. for making freeform scaffolds, much less a polymer scaffold made from a mold, to be used as a human implant. Rather, the devices of Mastrangelo et al. are for use in inkjet printheads, microdispensers and other mechanical devices for handling small volumes of liquid. Thus,

Mastrangelo et al.'s approach and process are completely incompatible with cells, tissues and 3D integration because the structures are built up using microelectronics-type processes incompatible with cells, and because the mechanical and fluidic integrity of the system is destroyed once the networks are separated from the rigid substrate.

Vacanti et al. teaches methods of solid free-form (SFF) fabrication such as three dimensional printing, but not micromachining molds. As a result, the resolution is a limited range, which is comparatively much less effective for the construction of engineered tissues than the claimed invention. Vacanti et al. therefore fails to teach or suggest structures such as microchannels (e.g., less than 250 microns in width or height) formed in polymer scaffolds by casting a scaffold on a mold made by micromachining.

For the §103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed.Cir. 1988). There must also be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowicz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993).

The cited references, taken either alone or in combination, are silent with respect to a motivation to combine the three references. As noted above, each reference is focused on certain approaches that are not easily combined. Taking Weiss et al. as the primary reference that teaches holding together individual layers with a barb (see Figures 10-12), how can you logically combine it with Mastrangelo et al. when Mastrangelo et al. teaches microfluidic devices fabricated permanently on a substrate? Mastrangelo et al. simply is not applicable to making freeform scaffolds for use in tissue engineering. Turning to Vacanti et al., it really adds very little beyond the teachings of Weiss et al. Vacanti et al. use SFF like Weiss et al. but merely include a notion of having pores in the scaffold. In short, there is no motivation for the skilled artisan to look to the teachings of Weiss et al., Mastrangelo et al. and/or Vacanti et al. to construct anything that looks like the claimed inventions because the various components would require an inventive step to be combined. Thus, the cited combination is not proper. Cima et al. and Marra et al. do not cure any of these deficiencies. Thus, reconsideration and withdrawal of

the rejections of Claims 25, 58 and each of the claims depending therefrom is respectfully requested.

Further, obviousness may also be rebutted by a showing that the prior art teaches away from the claimed invention. *In re Geisler*, 43 U.S.P.Q. 2d 1362 (Fed. Cir. 1997).

Mastrangelo et al. only contemplates creating cavities on a conventional CMOS substrate, e.g., a rigid silicon wafer and the like, in which layers are coated and patterned thereon. Mastrangelo et al. clearly teaches away from combination with Weiss et al. (and vice versa) because Weiss et al. discloses free form scaffold layers that are mechanically coupled together with barbs. These radically different approaches exclude the ability to interchange, or mix and match these teaching. Thus, the cited references teach away from each other and the combination is not proper. Accordingly, reconsideration and withdrawal of the rejections of Claims 25, 58 and each of the claims depending therefrom is respectfully requested.

Moreover, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). Here, the cited references fail to teach or suggest all limitations of the claimed invention.

In particular, the combination of the cited references fails to teach or suggest a multilayer device as recited by amended Claims 25 and 58. Claims 25 and 58 recite, *inter alia*, at least a first layer is fabricated by forming a mold using a semiconductor manufacturing process to then cast the at least a first layer on the mold. None of the cited references, alone or in combination, in whole or in part, teach or suggest such forming of a mold and casting on the mold. Therefore, Claim 25 and each of the claims depending therefrom as well as Claim 58 are not rendered obvious by the combination of references cited by the Examiner, and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Request for Interview


If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments and remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application, reconsideration, and withdrawal of the objections to and rejections of the application, and prompt issuance of a Notice of Allowance are respectfully requested.

Respectfully submitted,

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